MIME-Version:1.0
From:njdefiling@njd.uscourts.gov
To:ecfhelp@localhost.localdomain
Bcc:cfitzger@skadden.com, jrichter@winston.com,
njdnef_Hughes@njd.uscourts.gov,
njdnef_pisano@njd.uscourts.gov,
pdmuchowski@smithstratton.com, thastings@smithstratton.com
Message-Id:<2156415@njd.uscourts.gov>
Subject:Activity in Case 3:06-cv-03008-JAP-JJH JANSSEN PHARMACEUTICA N.V. et al v. BARR LABORATORIES, INC. et al Order Dismissing Case
Content-Type: text/html

*****NOTE TO PUBLIC ACCESS USERS*** You may view the filed documents once without charge. To avoid later charges, download a copy of each document during this first viewing.**

U.S. District Court

District of New Jersey [LIVE]

Notice of Electronic Filing

The following transaction was entered on 8/16/2007 at 2:49 PM EDT and filed on 8/16/2007

Case Name: JANSSEN PHARMACEUTICA N.V. et al v. BARR LABORATORIES, INC. et al

Case Number: 3:06-cv-3008

Filer:

WARNING: CASE CLOSED on 08/16/2007

Document Number: 15

Docket Text:
ORDER staying action with leave to reopen and DISMISSING CASE Signed by Judge Joel A. Pisano on 8/14/2007. (ss,)

3:06-cv-3008 Notice has been electronically mailed to:

16. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

Plaintiffs' Approved Drug Product

17. Janssen is the holder of an approved new drug application, NDA No. 21-615, for galantamine hydrobromide extended release capsules. That NDA was approved by FDA on April 1, 2005 and covers three strengths of capsule – Eq. 8 mg base, 16 mg base, and 24 mg base. The sole indication or condition of use for which galantamine hydrobromide extended release capsules are approved in NDA No. 21-615 is the treatment of mild to moderate dementia of the Alzheimer's type.

18. Pursuant to FDA's approval, Janssen currently markets galantamine hydrobromide extended-release capsules for the treatment of mild to moderate dementia of the Alzheimer's type under the trademark RAZADYNE ER®. Until last year, Janssen marketed its galantamine hydrobromide products under the trademark REMINYL®.

19. FDA has listed the '318 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-615.

20. The '318 patent qualifies for listing in the Orange Book in connection with NDA No. 21-615 because it claims an approved use of the drug product that is the subject of that NDA. Barr has never challenged the listing of the '318 patent in the Orange Book.

Barr's ANDA

21. Barr has represented that on or before May 19, 2006, it submitted to FDA an ANDA (ANDA No. 78-189) and paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for galantamine hydrobromide extended-release capsules purportedly bioequivalent to Plaintiffs' RAZADYNE ER® products. The purpose of Barr's ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide extended-release capsules before the expiration of the patents listed in the Orange Book for Janssen's NDA No. 21-615. Hence, Barr's purpose in submitting ANDA No. 78-189 is to market in the United States the galantamine hydrobromide products described therein before expiration of the '318 patent.

22. Upon information and belief, the sole condition of use for which Barr seeks approval in its ANDA No. 78-189 for its proposed galantamine hydrobromide extended-release capsules is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in Janssen's NDA No. 21-615.

23. Upon information and belief, the sole indication set forth in the proposed labeling submitted by Barr in its ANDA No. 78-189 for its proposed galantamine hydrobromide extended-release capsules is the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for Plaintiffs' REMINYL® and RAZADYNE ER® capsules.

Count 1: Patent Infringement

24. Plaintiffs reallege paragraphs 1 through 22 above as if fully set forth herein.

25. On May 5, 1987, the United States Patent and Trademark Office duly and legally issued the '318 patent, entitled "Method of Treating Alzheimer's Disease." The term of the '318 patent runs through December 14, 2008. A true and correct copy of the '318 patent is attached hereto as Exhibit A.

26. Synaptech is the owner of the '318 patent.

27. Janssen is the exclusive licensee under the '318 patent, pursuant to an exclusive license agreement between Synaptech and Janssen, of the right to develop, make, have made, keep, use, market, sell, and/or dispose of certain pharmaceutical preparations containing galantamine hydrobromide to treat Alzheimer's disease in the United States and other territories. Pursuant to that exclusive license, Janssen currently markets galantamine hydrobromide extended-release capsules in the United States under the trademark RAZADYNE ER® and previously marketed its galantamine hydrobromide products in the United States under the trademark REMINYL®. The conditions of use for which RAZADYNE ER® and REMINYL® are approved fall within one or more of the claims of the '318 patent.

28. As exclusive licensee, Janssen is authorized to enforce the '318 patent.

29. The conditions of use for which Barr seeks approval in its ANDA No. 78-189 fall within one or more of the claims of the '318 patent. If approved, use of

Barr's proposed galantamine hydrobromide products in accordance with the proposed labeling for those products submitted in ANDA No. 78-189 would constitute a use of the product claimed in one or more of the claims of the '318 patent.

30. Barr Labs is liable for infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 78-189 with a paragraph IV certification seeking FDA approval of ANDA No. 78-189 prior to expiration of the '318 patent. Barr Pharmaceuticals is liable for infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its causing ANDA No. 78-189 with a paragraph IV certification to be filed with FDA seeking approval of ANDA No. 78-189 prior to expiration of the '318 patent.

31. Upon information and belief, if approved, Barr's galantamine hydrobromide products for which approval is sought in Barr ANDA No. 78-189 will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer's type, which administration would constitute direct infringement of the '318 patent. Upon information and belief, this infringement will occur at Barr's behest, with its intent, knowledge, and encouragement, and Barr will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '318 patent.

32. Barr's offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '318 patent, of the galantamine hydrobromide products for which approval is sought in ANDA No. 78-189, would actively induce and contribute to infringement of the '318 patent, and Barr would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c). Barr's use in the United States of the galantamine

hydrobromide products in accordance with the labeling for which approval is sought in ANDA No. 78-189 prior to expiration of the '318 patent would infringe the '318 patent, and Barr would be liable as an infringer under 35 U.S.C. § 271(a).

33. Barr had actual and constructive notice of the '318 patent prior to filing its ANDA No. 78-189, and Barr's infringement of the '318 patent has been, and continues to be, willful.

34. Plaintiffs will be irreparably harmed if Barr is not enjoined from infringing or actively inducing or contributing to infringement of the '318 patent. Plaintiffs do not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Barr has infringed the '318 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment providing that the effective date of any FDA approval of the Barr ANDA No. 78-189 for galantamine hydrobromide extended-release Eq. 8 mg base, 16 mg base, and 24 mg base capsules be not earlier than the expiration date of the '318 patent;

C. A judgment declaring that Barr's manufacture, use, sale, offer for sale, or importation into the United States of the galantamine hydrobromide products for which approval is sought in ANDA No. 78-189 would constitute infringement of the '318 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

D. A permanent injunction enjoining Barr and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the galantamine hydrobromide extended-release capsules for which approval is sought in ANDA No. 78-189, or any galantamine hydrobromide product that infringes or induces or contributes to the infringement of the '318 patent, until expiration of that patent;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

s/Thomas E. Hastings
Thomas E. Hastings (TH0501)
SMITH, STRATTON, WISE, HEHER & BRENNAN, LLP
2 Research Way
Princeton, New Jersey 08540
Tel: (609) 924-6000
Fax: (609) 987-6651

Attorneys for Plaintiffs

Of Counsel:

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Kurt G. Calia
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel: 202-662-6000
Fax: 202-662-6291

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805
Fax: 732-524-5866

DATED: June 30, 2006

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

I hereby certify that to my knowledge the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/Thomas E. Hastings
Thomas E. Hastings

Dated: June 30, 2006

CYNTHIA V. FITZGERALD cfitzger@skadden.com

THOMAS EVAN HASTINGS thastings@smithstratton.com, pdmuchowski@smithstratton.com

JAMES S. RICHTER jrichter@winston.com

3:06-cv-3008 Notice will not be electronically mailed to::

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1046708974 [Date=8/16/2007] [FileNumber=2156413-0
]
[5dade164e0f2db0e76519ba1db31db3fc6e9c7b34f1c546dc6e1b8f2bc8a750aa4
96c8d31884b8f790658c6d975db2924983bdad40a1390303d7e696e6ff632]]

NOT FOR PUBLICATION **CLOSED**

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICA N.V., et al.,	:	
Plaintiff,	:	Civil Action No. 06-3008 (JAP)
v.	:	
BARR LABORATORIES, INC., et al.,	:	**ORDER**
Defendants.	:	

IT APPEARING that the parties have agreed to a stay of this patent infringement action pending the resolution of the matter of *In re: '318 Patent Infringement Litigation*, Case No. 05-356 (consolidated) (SLR) pending before Chief Judge Sue L. Robinson in the United States District Court for the District of Delaware, in which the validity of the patent-in-suit-in this action will be decided; and the Magistrate Judge having entered an order stating that "[s]ubject to the provision of this Order, this action is stayed pending further order of this Court" (dkt. entry no. 11, 3-2-07 Order); and

THE COURT having the inherent power to control the docket, *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936), *Rolo v. Gen. Dev. Corp.*, 949 F.2d 695, 702 (3d Cir. 1991); and the Court determining that, as the action has been stayed pending the resolution of the matter of *In re: '318 Patent Infringement Litigation*, Case No. 05-356 (consolidated) (SLR), the interests of judicial economy will be best served by administratively terminating this action; and thus the Court intending to administratively terminate this action, with leave to reopen when appropriate; and for good cause appearing; **IT IS**

ON this 14th day of August, 2007,

ORDERED that this action is administratively terminated, in addition to being stayed, with leave to reopen when appropriate; and

FURTHER ORDERED that the Clerk of the Court designate this action as closed.

SO ORDERED.

/s/ JOEL A. PISANO
United States District Judge

Thomas E. Hastings (TH0501)
SMITH, STRATTON, WISE, HEHER & BRENNAN, LLP
2 Research Way
Princeton, New Jersey 08540
Tel: (609) 924-6000
Fax: (609) 987-6651

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Kurt G. Calia
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel: 202-662-6000
Fax: 202-662-6291

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805
Fax: 732-524-5866

Attorneys for Plaintiffs Janssen Pharmaceutica N.V.,
Janssen, L.P. and Synaptech, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., ORTHO-MCNEIL NEUROLOGICS, INC., and SYNAPTECH, INC.,	)	Civ. Action No._____
Plaintiffs,	)	
v.	)	**COMPLAINT FOR PATENT INFRINGEMENT**
BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.,	)	
Defendants.	)	

Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Ortho-McNeil Neurologics, Inc. (collectively, "Janssen"), and Synaptech, Inc. (collectively, "Plaintiffs"), by their attorneys, for their complaint against Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr"), allege as follows:

The Parties

1. Plaintiff Janssen Pharmaceutica N.V., a wholly owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

2. Plaintiff Janssen, L.P., a wholly owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

3. Plaintiff Ortho-McNeil Neurologics, Inc., a wholly owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. Plaintiff Synaptech, Inc. ("Synaptech") is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

5. Upon information and belief, Defendant Barr Laboratories, Inc. ("Barr Labs") is a corporation organized and existing under the laws of the State of

Delaware, with its principal place of business at 2 Quaker Road, Pomona, New York 10970, and manufacturing facilities at 265 Livingston Road, Northvale, New Jersey 07647, that purchased with the aid of funding from the New Jersey Economic Development Authority. Barr Labs is registered to do business and does business in the State of New Jersey.

6. Upon information and belief, Defendant Barr Pharmaceuticals, Inc. ("Barr Pharmaceuticals") is a corporation organized and existing under the laws of the State of Delaware and maintains executive offices at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Barr Pharmaceuticals is registered to do business and does business in the State of New Jersey. Barr Pharmaceuticals is the ultimate parent of Barr Labs, and Barr Labs is a wholly owned subsidiary of Barr Pharmaceuticals.

7. Upon information and belief, Barr Labs and Barr Pharmaceuticals collaborated in the research and development of Barr's Abbreviated New Drug Application ("ANDA") No. 78-189 for galantamine hydrobromide extended-release capsules, continue to collaborate in seeking approval of that application from the Food and Drug Administration ("FDA"), and intend to collaborate in the commercial manufacture, marketing, and sale of galantamine hydrobromide products, including commercial marketing and sale in the State of New Jersey, in the event that FDA approves Barr's ANDA No. 78-189. Upon information and belief, Barr Labs and Barr Pharmaceuticals collaborate in the manufacture, marketing, and sale of many pharmaceutical products, including numerous generic prescription drug products manufactured and sold pursuant to an approved abbreviated new drug application, that are marketed and sold to customers in the State of New Jersey.

Jurisdiction and Venue

8. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 4,663,318 ("the '318 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Barr Labs is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its having conducted business in the State of New Jersey, having availed itself of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State.

10. Barr Pharmaceuticals is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its having conducted business in the State of New Jersey, having availed itself of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for Approval of New and Generic Drugs

12. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

13. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an abbreviated new drug application for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the pioneering drug, or, if the rate of absorption differs, that such difference is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(8)(B).

14. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

15. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).